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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,952	03/22/2002	Stephen H. Leppla	15280-4051US	4741

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Annette S Parent
Townsend & Townsend & Crew
8th Floor
Two Embarcadero Center
San Francisco, CA 94111-3834

EXAMINER

FETTEROLF, BRANDON J

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,952	LEPPLA ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Leppa *et al.*

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-3, 6, 8-9, 11-14, and 17-22, as specifically drawn to the special technical feature of a therapeutic method of targeting a native lethal factor to a cancer cell over expressing a matrix metalloprotease.

Group 2, claim(s) 1, 4-5, 7-9, 11-14, and 17-22, as specifically drawn to the special technical feature of a therapeutic method of targeting a native lethal factor to a cancer cell over expressing a plasminogen activator or a plasminogen activator receptor.

Group 3, claim(s) 1-3, 6, 8-9, 15-16, and 19-22, as specifically drawn to the special technical feature of a diagnostic method of targeting a native lethal factor to a cancer cell over expressing a matrix metalloprotease.

Group 4, claim(s) 1, 4-5, 7-9, 15-16, and 19-22, as specifically drawn to the special technical feature of a diagnostic method of targeting a native lethal factor to a cancer cell over expressing a plasminogen activator or a plasminogen activator receptor.

Group 5, claim(s) 1-3, 6, 10-14, and 17-22, as specifically drawn to the special technical feature of a therapeutic method of targeting a native lethal factor to an inflammatory cell over expressing a matrix metalloprotease.

Group 6, claim(s) 1, 4-5, 7, 10-14, and 17-22, as specifically drawn to the special technical feature of a therapeutic method of targeting a native lethal factor to an inflammatory cell over expressing a plasminogen activator or a plasminogen activator receptor.

Group 7, claim(s) 1-3, 6, 15-16, and 19-22, as specifically drawn to the special technical feature of a diagnostic method of targeting a native lethal factor to an inflammatory cell over expressing a matrix metalloprotease.

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Group 8, claim(s) 1, 4-5, 7, 15-16, and 19-22, as specifically drawn to the special technical feature of a diagnostic method of targeting a native lethal factor to an inflammatory cell over expressing a plasminogen activator or a plasminogen activator receptor.

Group 9, claim(s) 23-24, as specifically drawn to the special technical feature of an isolated mutant protective protein comprising a matrix metalloproteinase or plasminogen activator-recognized cleavage site in place of the native protective antigen furin-recognized cleavage site.

Note: Upon election of any one of Groups 1-9, the applicant must choose ONE SEQ ID NO from those listed in Claims 6-7 or 24, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

Accordingly, since the claims include different chemically unrelated products (i.e. six chemically different recognized cleavage sites characterized by six different amino acid sequences), and multiple methods (therapeutic or diagnostic methods for targeting cancer or inflammatory cells) of using said products as delineated in the groups above, Groups 1-9 are not so linked as to form a single general inventive concept and restriction is proper.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Groups 1-4, claim 9, are generic to the following species of cancer such as; lung cancer, breast cancer, bladder cancer, thyroid cancer, liver cancer ... melanoma, monocytic leukemia, and myelogenous leukemia.

Groups 1, 3, 5, 7, and 9, claim 3, are generic to the following species of matrix metalloproteinase:

- 1) MMP-2 (gelatinase A)
- 2) MMP-9 (gelatinase B)
- 3) membrane-type 1 MMP (MT1-MMP)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The products of the above species represent cell types with different morphologies and functions such that one species could not be interchanged with the other. In addition, the products of the above species represent separate and distinct enzymes different in chemical structure and function such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF


GARY NICKOL
PRIMARY EXAMINER